AUG 2 4 2000

K000401

510K Summary

1. Sponsor Name: Vapotherm Inc.
   163 Conduit St
   Annapolis, MD 21401

2. Device Name: Vapotherm™ 2000*i*

3. Identification of Predicate or Legally Marketed Device: Transpirator™ MT 1000, Fisher-Paykel MR 850

4. Device Description: The Vapotherm 2000*i* and the Transpirator™ MT 1000 share the concept of humidification by transpiration of water vapor across a membrane. Both produce a high flow of highly humidified air (relative humidity>95%), virtually free of droplets, at body temperature or above. The water content at 41°C is 40-50 mg/liter, about fourfold higher than can be achieved by humidification at room temperature. The unique combination of high flow and vapor-phase humidity allow an unusually wide range of clinical applications. Applications previously considered impractical because of limited patient tolerance for high nasal flow can now be routine because of the comfort provided by warmth and high humidity.

   Safety

   The Vapotherm™ 2000*i* has been designed with patient comfort and safety in mind. While humidifiers in general pose very little risk to the patient, the Vapotherm™ 2000*i* advanced safety features effectively reduce all potential humidifier risks to negligible levels.

   Electrical Safety

   The electrical components of the Vapotherm™ 2000*i* are protected from water. The casing also protects electrical components from accidental water spills which cannot enter through air vents. The power cord is permanently attached and there is no hardware power switch so that risk of electric shock is virtually eliminated. However, if the Vapotherm™ 2000*i* should be wetted or immersed in water it should be returned to the manufacturer for safety inspection before any further patient use.

Thermal safety

No external part of the Vapotherm™ 2000*i* has a surface temperature above 41°C and so there is no risk of patient burning. The Vapotherm™ 2000*i* is protected against overheating by software that continually monitors water temperature. If the temperature rises above the set point an alarm sounds. If the temperature continues to increase the unit is shut off and cannot be restarted.

Bacteriological safety

Air and water are separated by a biological barrier in the membrane cartridge as the membrane pore size excludes bacteria. Thus under normal working conditions there is essentially no risk of bacterial contamination of the nasal air flow. Penetration of water through a damaged membrane into the air system is prevented by the sensor described below under "airway protection".

Airway protection

In the event of a leak developing within the humidifier cartridge, water from the circulation could potentially enter the air tubing and be forced towards the patient airway. To safeguard the patient from water and potential bacteriological hazard, the presence of liquid water in the air tubing will cause an instant shutdown of the unit, at the same time as the flow of gas is shut off by means of a solenoid valve.

5. Intended Use: The Vapotherm™ 2000*i* is intended to add moisture to and to warm breathing gases for administration to a patient.

6. Technological Characteristics: The Vapotherm produces a high flow of highly humidified air (relative humidity >95%), virtually free of droplets, at body temperature or above. The water content at 41°C is 40-50 mg/liter, about fourfold higher than can be achieved by humidification at room temperature. Because the water is almost all in the vapor phase there is little or no impaction of droplets in the upper airway and the vapor content is available to the entire pulmonary airway. At this very high water content, to avoid condensation the air temperature must be maintained constant between the Vapotherm and the patient. This is achieved by heating the air delivery tube using circulating hot water.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 2000

Mr. Robert Storey
Vapotherm, Inc.
163 Conduit Street
Annapolis, MD 21401

Re: K000401
Vapotherm™ - 2000I
Regulatory Class: II (two)
Product Code: BTT
Dated: May 26, 2000
Received: May 30, 2000

Dear Mr. Storey:

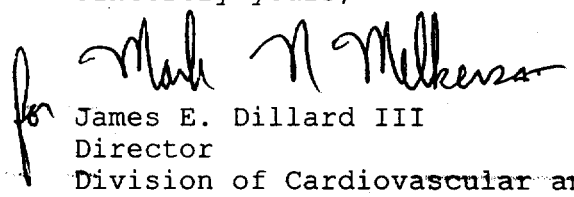
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (If known) K000401

Device name: Vapotherm™ 2000i

Indication for Use Vapotherm™ 2000i is designed for use to add moisture to and to warm breathing gases for administration to a patient.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device evaluation (ODE)

for Mark N Miller

Division of Cardiovascular & Respiratory Devices

510(k) Number K000401

Prescription Use ✓ OR Over-The-Counter-Use____

(Per 21 CFR 801.109)